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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,539	03/15/2005	Karin Butz	085449-0158	3633

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EXAMINER	
GODDARD, LAURA B	
ART UNIT	PAPER NUMBER
1642	
MAIL DATE	DELIVERY MODE
10/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/519,539	**Applicant(s)** BUTZ ET AL.	
	Examiner LAURA B. GODDARD	**Art Unit** 1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 June 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *6* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *27 June 2008*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *58-62 and 64*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Laura B Goddard/
Examiner, Art Unit 1642

Continuation of 11. does NOT place the application in condition for allowance because: Claims 58-62 and 64 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Applicants argue that A) they have provided a genus of peptides having sequence identity and homology to SEQ ID NO:127. Applicants argue the specification teaches 132 peptides that bind livin-beta and point to peptide No. 43 of Table 1 that has 19 positions the same as SEQ ID NO:127, and point to Peptide No. 39 that has 16 identical amino acid residues as SEQ ID NO:127. Applicants argue that these peptides with even less than 90% idetnity bind to livin-beta and are capable of sensitizing cells for apoptosis. Applicants argue that the specification teaches that the amino acids "AEIYES", the last 6 carboxyterminal amino acids of most peptides can be omitted without losing funcitonal properties of the peptides and Applicants point to p. 4 of the specification for this support. Applicants argue that they teach the structural elements which can be eliminated without affecting the claimed functional features (p. 2-3). Applicants argue B) the claims recite two functional limitations for peptides at least 90% identical to SEQ ID NO:127 and these two functional characteristics correlate with peptide structure. Applicants argue that one skilled in the art would have known that functional characteristics of peptides which are at least 90% identical to SEQ ID NO:127 correlate with the function of the peptide having SEQ ID NO:127. Applicants argue the specification teaches 132 pepides that bind livin-beta and sensitize cell for apoptosis and they have even less than 90% identity to SEQ ID NO:127, indicating Applicants were in possession of more than the claimed genus. Applicants argue C) a person skilled in the art needs only to be able to identify peptides which are at least 90% identical to the peptide having the amino acid sequence shown in SEQ ID NO:127 and that this can be done wihtout undue experimentation. The specification teaches how to screen for such peptides at page 5 (p. 3-4).

The arguments have been considered but are not found persuasive. The only shared core structure of most of the peptides disclosed in the specification is the very "AEIYES" sequence that the specification teaches can be removed and is not necessary for function. The specificaiton does not identify any sequence of SEQ ID NO:127 that is critical to the function of sensitizing cells for apoptosis or binding livin-beta. This is even more apparent when the shared "AEIYES" sequence is removed from the peptides, the disclosed peptides do not share a core sequence or conserved structure that allows one of skill iin the art to readily identify the genus of peptides having 90% identity to SEQ ID NO:127 that still function as claimed. Applicants state that many of these peptides share less than 90% identity with each other, supporting Examiner's argument that there is no apparent core or conserved sequence shared among peptides that function as claimed. The specification and claims do not identify which structural features are conserved among the peptides comprising an amino acid sequence at least 90% identical to SEQ ID NO:127, or which structures constitute a substantial portion of the genus in order for one to visualize or recognize the identity of the members of the genus, hence the written description for the genus peptides in the claimed methods do not meet the standards of Lilly. Although the specification discloses SEQ ID NO:127, the specification does not provide adequate written description according to the standards of Enzo because there are no specific structures, identifying characteristics, partial or complete structures, or functional characteristic coupled with a known or disclosed structure for the broad genus of peptides with at least 90% identity to SEQ ID NO:127, other than SEQ ID NO:127 itself, as recited in the claims. The list of peptides disclosed in the specification do not share a core or conserved structure required for the claimed functions and are not representative species of the peptide genus as claimed. Arguments drawn to screening without undue experimenation are not persuasive because they are drawn to enablement and are not applicable to the written description analysis. In any event, screening assays do not enable the claimed invention because the court found in (Rochester v. Searle, 358 F.3d 916, Fed Cir., 2004) that screening assays, are not sufficient to enable an invention because they are merely a wish or plan for obtaining the claimed chemical invention. The claims remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record.